

ESSENTIO™ MRI Pacing System

Models L110, L111

- Provides an ImageReady™ MR Conditional pacing system* at 3T and 1.5T, full body, with no time limitations, with automatic MRI timeout feature to optimize workflow in the MR environment
- RF telemetry for wireless transmission of information and efficiency in the operating room and follow-up setting
- Automatic Daily Monitoring with the LATITUDE™ NXT Patient Management System
- Automaticity with PaceSafe™ RV and RA, providing dynamic adjustment of pacing outputs to ensure capture and Automatic Gain Control to dynamically adjust the sensitivity in both the atrium and the ventricle, to maximize efficiency and ease of use
- RightRate™ MV sensor is the only sensor clinically proven to restore chronotropic competence¹
- AV Search +, designed to minimize unnecessary RV pacing without clinically significant pauses, therefore reducing the risk of HF development
- Enhanced features and diagnostics designed to provide you with greater insight into your patient's disease progression
- POST function to facilitate patient follow up with a fully automatic device and lead check
- EASYVIEW™ header with port identifiers designed to make the implant experience more efficient

*When conditions of use are met, please refer to MRI Technical Guide.



Mechanical Specifications

Model	Type	Size (cm) (W x H x D)	Mass (g)	Volume (cc)	Connector Type (RA RV LV)
L110	SR	4.45 x 4.81 x 0.75	23.6	11.7	RA/RV: IS1
L111	DR	4.45 x 5.02 x 0.75	24.8	12.2	RA: IS1 – RV: IS1

Longevity

Projected Longevity	Pacing Amplitude	Pacing	MV Sensor	500Ω	750Ω	1000Ω
SR						
Typical programmed setting	2.5	100%	On	9.2	9.7	10.0
Maximum labeled longevity**	2.0	50%	Off	11.1	11.3	11.5
DR						
Typical programmed setting	2.5	100%	On	7.6	8.2	8.7
Maximum labeled longevity**	2.0	50%	Off	10.0	10.3	10.5

Additional Longevity Information

- Settings: LRL 60bpm, ventricular and atrial settings of 0.4 ms pacing pulse width; sensors On; EGM Onset On. These calculations also assume that the pulse generator spends 6 months in Storage mode during shipping and storage, the ZIP™ telemetry use for 1 hour at implant time and for 40 minutes annually for in-clinic follow-up checks.
- Power Supply SR and DR models: lithium-carbon monofluoride cell; Boston Scientific; 402290.

**No MV Sensor.

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Pacing Therapy

Brady Modes	Normal:DDD(R)-DDI(R)-VDD(R)-VVI(R)-AAI(R)-DOO-VOO-AOO-Off Temporary: DDD-DDI-VDD-VVI-AAI-DOO-VOO-AOO-Off
AT/AF Management	ATR Mode Switch, Rate Smoothing
Automaticity	Automatic Gain Control (AGC) for sensitivity Right Atrial Automatic Threshold (RAAT) Right Ventricular Automatic Capture (RVAC)
Rate Adaptive Pacing	Accelerometer, RightRate™ (Minute Ventilation) or blended sensors with sensor trending function
RV Pacing Reduction	AV Search +, AV Delay to 400 ms, Rate Hysteresis
Rate Management	Sudden Brady Response (SBR), PMT Termination, PVARP after PVC, Dynamic PVARP
Pace/Sense Configuration	Unipolar, Bipolar, Bipolar/Unipolar, Unipolar/Bipolar, Unipolar/Off, Bipolar/Off, Lead Safety Switch, Automatic Lead Recognition

Patient Diagnostics

Arrhythmia Logbook	Event Summary, Stored Electrograms with Annotation Markers (Intervals and approximately 14 minutes all multi channel EGM, always with 10 seconds Onset and event storage prioritization). Implant activation of all available EGMs. On screen measurements of all stored signal, amplitudes and timing. Snapshot Function (up to 12 seconds trace of ECG/EGM display stored)
Histograms & Counters	Ventricular Tachy Counter, Brady Counter, Histograms, Intrinsic Promotion (Rate Hysteresis % successful and AVSH+ % successful)
Diagnostics	AT/AF Burden, A & V Arrhythmias, Weight and Blood Pressure*
DAILY TREND for last 365 Days	Events, AT/AF Burden, Heart Rate, Lead Impedance and Amplitude, RAAT Trend, RVAC Trend

*Weight and Blood Pressure are only available via LATITUDE NXT.

ImageReady™

MRI Lead Selection	Pulse Generator MR-conditional with all FINELINE™II Sterox, FINELINE™II Sterox EZ and INGEVITY™ Pacing Lead Models
MRI Conditions	Full body scan at 3T and 1.5T (\leq SAR 2W/Kg) for all FINELINE™II models** Full body scan at 3T and 1.5T (\leq SAR 4W/Kg) for all INGEVITY™ MRI models**
MRI Mode	Pacing Mode: AOO,VOO,DOO,Off Protection Time Out: Off, 12,24,48 hours

**Please refer to the Pacing System MRI Technical Guide as the system is designated as MR Conditional in accordance with specified conditions.

Implant/In Clinic Follow Up

Implant Communication Mode	Programmable values: Enable use of ZIP™ telemetry (MICS) (Requires initial use of wand for device ID) or use wand for all telemetry Nominal: Enable use of ZIP™ telemetry (Requires initial use of wand for device ID)
In Clinic Follow Up	Snapshot Function up to 12 seconds trace of ECG/EGM display stored POST (Post-Operative System Test): provides an automatic device/lead check at a pre-determined time post-implant to help document proper system functionality without requiring manual system testing

Remote Follow Up

Remote Monitoring	This device is designed to be LATITUDE™ NXT enabled; LATITUDE NXT availability varies by region***
Thresholds	Automatic storage of last successful daily PaceSafe threshold test for all active chambers
Wireless	Remote follow-up for all devices (MICS)
Patient Triggered Monitor (PTM)	Triggers the storage of two minutes onset and one minute post – EGMs, intervals, and annotated marker data during a symptomatic episode by placing a magnet over the device

***LATITUDE™ NXT is not available for L100 and L101 models.

Safety Functions****

Safety Core	Is intended to provide life-sustaining therapy if certain non-recoverable or repeat fault conditions occur. Safety Core operates independently and acts as a backup to these components
Electrocautery Protection Mode	Provides asynchronous pacing at the programmed outputs and LRL when commanded by the programmer

****The Safety Functions do not have programmable parameters.

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1. Chronotropic competence is defined by the Model of the Cardiac Chronotropic Response to Exercise. Wilkoff B, Corey J, Blackburn G. A mathematical model of the cardiac chronotropic response to exercise. Journal of Electrophysiology. 1989;3:176–180.

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